

Philadelphia FIGHT  
Institutional Review Board  
**PROTOCOL PROGRESS REPORT**

Annual    Semi-Annual    Quarterly    Completion/Termination    Special Review    Monthly

Principal Investigator: Karam Mounzer, MD

Date: 30 Oct 2019

Protocol #: 212355

Title:

**The following information is provided for studies conducted during the period (29 May 2019) to (30 Oct 2019) under the protocol identified above.**

1.  **Re-approval** - Complete 2 through 7, sign and submit the following: this form, a brief progress report for the period since the last IRB approval Note: The consent form (now in use) and any other required documentation, will be made available if necessary (see #4 and #5).  
 **Re-approval, Data Analysis only** - Complete 2 through 7, sign and submit the following: this form, a brief progress report for the period since the last IRB approval.  
 **Termination** (study closed - no patients still being followed) - Complete 2 through 5, sign and return the original of this form with any supporting documentation.  
 **Special Review** complete 2 through 7.
2. Have you performed any research involving human subjects since the last re-approval?  Yes  No
3. a)  Target Enrollment  
b)  How many subjects were enrolled since the last reapproval?  
c)  Total subjects enrolled to date since the study began.  
d) Are signed consents available for all subjects?  Yes  No
4. a)  How many serious adverse events (SAEs) were encountered at Philadelphia FIGHT within this review period?  
b)  How many SAEs have been reported at Philadelphia FIGHT since the beginning of the study?
5. Enter the number of subjects enrolled in each category to date.

Gender▼/Race►	Hispanic							non-Hispanic							UnK	Total	
	NA	AS	AA	PI	WH	MR	OT	NA	AS	AA	PI	WH	MR	OT	UnK		
Female																	
F→M																	
Male																	
M→F																	
Gender Nonconforming																	
Total																	0

NA = American Indian/Alaskan Native      WH = White, Caucasian  
AS = Asian      MR = Multiracial  
AA = African American/Black      OT = other  
PI = Native Hawaiian, Pacific Islander      UnK = unknown/did not report

6. a) Has there been a change to the protocol or consent form since the last progress report?  No  Yes  
b) If yes, please describe below and indicate if this change has already been approved?  No  Yes
7. a) Have there been any changes in investigators since the last approval?  No  Yes  
b) If yes, indicate the changes:

Add: \_\_\_\_\_

Delete: \_\_\_\_\_

Date: \_\_\_\_\_

Principal Investigator's Signature \_\_\_\_\_

